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08/716,169	12/17/1996	STEPHEN M. ANDERTON	961125	5487

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EXAMINER	
NOLAN, PATRICK J	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 1203

Application Number: 08/716,169
Filing Date: December 17, 1996
Appellant(s): ANDERTON ET AL.

Barbara E. Johnson
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 8-27-03.

A statement identifying the real party in interest is contained in the brief.

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

The statement of the status of the claims contained in the brief is correct.

No amendment after final has been filed.

The summary of invention contained in the brief is correct.

The appellant's statement of the issues in the brief is correct.

The rejection of claims 24-30 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

The copy of the appealed claims contained in the Appendix to the brief is correct.

Anderton et al. "Peptide-based immunotherapy of autoimmunity: a path of puzzles, paradoxes and possibilities" Immunology, Vol. 104, pp 367-376(2001).

Wendling et al., "A conserved mycobacterial heat shock protein (hsp) 70 sequence prevents adjuvant arthritis upon nasal administration and induces IL-10 producing T cells that cross react with the mammalian self-hsp 70 homologue" Vol. 164, (2000) pp 2711-2717.

Grounds of rejections:

1. Claims 24-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using the recited peptides for treating or protecting against experimentally induced adjuvant arthritis or atherosclerosis, does not reasonably provide enablement for treating or protecting any inflammatory disease, particularly autoimmune diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims.

Anderton et al., one of the Appellant's, in reviewing the usefulness of altered peptide ligand (APL) therapy in humans concluded against the use of APL's in human autoimmune disorders, even though animal data was very promising, and that such an approach in an outbred human population might aggravate rather than reduce pathology (page 370, 1st paragraph 2nd column). In addition, Wendling et al., of which two of the authors are co-inventors, clearly teaches that route of administration, nasal worked while parenteral did not, appears to be critical in treating autoimmune diseases with conserved mycobacterial heat shock proteins. Wendling et al., reasons that the stimulation of IL-10 production for bystander suppression appears to be critical for tolerance induction. It is recently known that nasal

administration favors IL-10 production while other routes (parenteral) do not. However, such a fine tuning of administration was not disclosed by the instant Application, but appears critical to the enablement of the claimed invention.

Response to Appellant's arguments:

1. Claims 24-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using the recited peptides for treating or protecting against experimentally induced adjuvant arthritis or atherosclerosis, does not reasonably provide enablement for treating or protecting against any inflammatory disease, particularly autoimmune diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims.

Appellant argues that the specification provides sufficient guidance on the enablement of their invention by providing detail as to which amino acid sequences should be selected but also documents the lymph node responses to administration of the inventive peptides and this demonstration provides evidence for treating all known forms of inflammation.

One of the main thrusts of the Anderton et al., teaching is that in vivo animal studies are not applicable to predicting treatment in human disease due to the fact that humans are an outbred population while most animal models used are inbred and display limited T cell repertoires, page 370 in particular.

Appellant argues the evidence supplied by Professor van Eden in his declaration are entitled to greater weight than any unsupported assertions by the Examiner.

The declaration supplied was considered and as a result the Examiner modified the rejection from a total lack of enablement to a scope of enablement rejection. Furthermore, the

Examiner has relied upon evidence disclosed by Appellant in their own publication to support the legal position that the use of the claimed peptides for human treatment or protection is unpredictable.

Appellant argues that In re Wright, 999 F.2d 1557, 27, U.S.P.Q. 2d 1510 (1993), no longer applies because Appellant has provided in excess or one working example, as well as much comparative data to support a broad scope of enablement. Thus In re Hogan 595 F.2d 595, 194 U.S.P.Q. 527 (1977) continues to apply.

The fact pattern in the instantly filed case and In re Wright, 999 F.2d 1557, 27, U.S.P.Q. 2d 1510 (1993) are very similar. Both cases had one working example and guidance on how to practice the full the scope of the invention and in both cases the Examiner applied a lack of scope of enablement based on a post dated filing reference which stated the scope of the invention recited in the claims was not enabled.

Appellant argues their invention is directed to inducing regulatory T cells specific for heat shock protein and because the expression of heat shock protein is enhanced in inflamed tissue, the induced regulatory T cells are ideal to treat inflammation. Appellant argues that Anderton does not speak of such peptide treatments, so the reference is not relevant to comment on the predictability of the of claimed invention.

However, Anderton et al., specifically teaches administering mycobacterial heat shock proteins to treat diseases in animal models, page 368, and while these peptides are useful in animal model treatments, they are not useful in human outbred populations (page 370). Furthermore, Applicants assertion that the claimed invention induces regulatory T cells, is just that, assertion. There is no evidence of induction of regulatory T cells in Appellant's disclosure. In fact Anderton et al., teaches the switch from Th1 to Th2 (i.e. regulatory T cells) by use of APL's, but he goes on to state that inducing Th2 immune responses is problematic because of the complexity of the T cell repertoire, the unpredictability of the

effects of APL and the harmful hyper-reactivity of the APL. So, Anderton speaks volumes on the problems associated with APL's being used to induce "regulatory" T cells.

Appellant argues their claimed invention is not what Anderton et al., defines as an APL. The peptides Appellant is claiming to administer are bacteria derived heat shock proteins that have homology to mammalian heat shock proteins. They are not identical in sequence to the naturally occurring T cell epitope, so they are within Anderton's definition of APL, altered peptide ligand. Furthermore, contrary to Appellant assertion, Anderton does discuss mycobacterial derived heat shock proteins for treatment, page 368, 2nd column.

Appellant argues the disclosure in Wendling et al., is not on point because route determination are developed by those of skill in the art as the art develops and so the invention inheres in knowing which peptide to administer, after all, not do much in how to do so.

Without the knowledge of Wendling et al., the claimed invention would not predictably work. The nasal route was not even contemplated by Appellant's disclosure.

For the above reasons, it is believed that the rejections should be sustained.

Respectively submitted,

Patrick J. Nolan, Ph.D.
Primary Examiner
12/12/03

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